

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Karen M. Williams,
Magistrate Judge

Honorable Thomas Vanaskie
(Ret.), Special Discovery Master

**THE ZHP PARTIES' REPLY BRIEF IN SUPPORT OF THEIR MOTION
FOR A PROTECTIVE ORDER PRECLUDING THE DEPOSITION OF
ZHP PRESIDENT BAOHUA CHEN**

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INTRODUCTION

Plaintiffs' stated need for Mr. Chen's deposition demonstrates why Mr. Chen is the quintessential apex witness whose testimony should be precluded under the apex doctrine. Their Opposition to ZHP's Motion for a Protective Order Precluding the Deposition of Baohua Chen ("Opposition," Dkt. 1298) asserts that Plaintiffs need Mr. Chen's deposition to understand [REDACTED]

[REDACTED]

Opp. at 21-22. Plaintiffs want to depose Mr. Chen precisely *because* he is the apex of ZHP. *See id.* at 18 [REDACTED]

[REDACTED]

However, the fact that Mr. Chen, as the President of ZHP, may be considered the ultimate head of its departments and subsidiaries does not entitle Plaintiffs to his deposition. A Court may for good cause issue an order protecting a person from the undue burden of a deposition. In the case of an apex witness, there is a rebuttable presumption that the deposition would be an undue burden where there is a more convenient, less burdensome, and less expensive alternative. That is the case here.

As explained in the ZHP Parties' Brief in Support of their Motion to Preclude the Deposition Testimony of ZHP President Baohua Chen ("Opening Brief," Dkt. 1247), and Supplemental Brief in Support of the Motion ("Supplemental Brief," Dkt. 1295), Plaintiffs have had open access for months to depose ***17 ZHP Party witnesses***

(11 from ZHP, including the Vice Chairman of ZHP's Board, Jun Du, and the heads of ZHP's production, quality assurance, quality control, regulatory, CEMAT, and API and finished dose sales departments; the CEO of Syncores; the CEO of Prinbury BioPharm; and the CEO of Princeton Pharmaceuticals and Solco Healthcare) and Plaintiffs have covered all **59 30(b)(6) topics** and much more (not to mention the more than 350,000 documents produced by the ZHP Parties). These ZHP Party witnesses, both 30(b)(6) corporate deponents and fact witnesses, have provided thousands of pages of testimony during the **164.5 hours** of total ZHP Party testimony (not counting additional translation time) available to Plaintiffs detailing each department and entity's role in developing, manufacturing, process changes, quality assurance and control, FDA plant inspections, regulatory compliance, valsartan sales and pricing, and investigations as well as process changes following the discovery of nitrosamines in valsartan. Plaintiffs therefore already have had access to and the opportunity to question the people most knowledgeable about all of these at-issue topics.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Plaintiffs strain to show that Mr. Chen has some knowledge about facts at issue, but the apex doctrine

requires more; it requires that Mr. Chen have unique knowledge about material facts. Given the truly gargantuan record of ZHP Party discovery, all of which demonstrates Mr. Chen's lack of unique knowledge regarding material facts, Plaintiffs have not rebutted—nor could they—the apex doctrine's presumption of undue burden (expressly recognized by Third Circuit precedent).

Accordingly, for the reasons discussed below, and as presented in the ZHP Parties' Opening Brief and Supplemental Brief, which are incorporated herein, the Court should grant the ZHP Parties' Motion for a Protective Order and preclude the apex deposition of Mr. Chen.

ARGUMENT

I. PLAINTIFFS ARE REQUIRED TO REBUT THE PRESUMPTION AGAINST MR. CHEN'S DEPOSITION UNDER THE APEX DOCTRINE

Plaintiffs try to imply that the apex doctrine—including its rebuttable presumption of undue burden—is inapplicable. Attempting to minimize the apex doctrine, Plaintiffs provide scant attention to the decisions of courts within this Circuit, including a decision of this Court, characterizing them as inapposite or mere “unpublished trial court decisions.” Opp. at 1 & 23. Yet Plaintiffs cannot deny that “[c]ourts in this circuit”—*the Third Circuit*—adhere to the apex doctrine. *Younes v. 7-Eleven, Inc.*, No. CV 13-3500 (RMB/JS), 2015 WL 12844446, at *2 (D.N.J. Aug. 19, 2015) (Schneider, J.) (citation omitted).

It is indisputable (and undisputed) that our Circuit's courts "have adopted rules" regarding "whether a court should permit the deposition of a high-ranking corporate executive" under the apex doctrine. *Ford Motor Co. v. Edgewood Properties, Inc.*, No. CIV.A. 06-1278 WJM E, 2011 WL 677331, at *2 (D.N.J. Feb. 15, 2011) (citing *Piontek v. I.C. Sys.*, No. CIV. 1:08-1207, 2008 WL 7674787, at *1 (M.D. Pa. Oct. 22, 2008)); *Roman v. Cumberland Ins. Grp.*, No. CIV. A. 07-CV-1201, 2007 WL 4893479, at *1 (E.D. Pa. Oct. 26, 2007); *Reif v. CNA*, 248 F.R.D. 448, 451 (E.D. Pa. 2008).

Plaintiffs argue against the characterization of the apex doctrine by the court in *United States ex rel. Galmines v. Novartis Pharms. Corp.*, No. CV 06-3213, 2015 WL 4973626, (E.D. Pa. Aug. 20, 2015) (Pratter, J.), that "[t]he apex doctrine ... appl[ies] **a rebuttable presumption** that a high-level official's deposition represents a significant burden upon the deponent." *Id.* at *2.¹ Opp. at 28. Yet Judge Pratter's characterization is common sense, because unlike a deposition for any other witness, a party seeking to depose an apex witness must show that the apex possesses (1) unique knowledge of material issues that (2) cannot be discovered through "lower-

¹ The undue burden on Mr. Chen were he to be deposed is compounded because he would be required to travel outside of mainland China for the deposition, and due to the time zone difference and the 75% additional time allotted under the deposition protocol because Mr. Chen does not speak English, the deposition would have to be conducted over the course of three days (two 5-hour blocks and one 2.5 hour block), as opposed to a single 7-hour deposition day.

level employees or *through less burdensome means.*” *Younes*, 2015 WL 12844446, at *2 (emphasis added). In other words, the apex doctrine is a rule that characterizes the burden of an apex deposition as “undue absent the two factors set forth in the apex doctrine, which go to the lack of a more convenient, less burdensome, and less expensive alternative.” *United States ex rel. Galmines*, 2015 WL 4973626 at *2 (emphasis added). This Court, and every other court within this Circuit, applies the apex doctrine in this exact way. *See, e.g., Younes*, 2015 WL 12844446, at *2; *Ford Motor Co.*, 2011 WL 677331, at *2; *Roman*, 2007 WL 4893479, at *1; *Reif*, 248 F.R.D. at 451. Thus, as with Plaintiffs’ disregard of this Court’s decision in *Younes*, Plaintiffs’ “analysis” of the apex doctrine rings hollow, amounting to denigration and empty advocacy.

While, beyond doubt, the party “seeking to quash a subpoena” or moving for a protective order bears the burden of proof, “[t]he apex doctrine is ... a tool for guiding the Court’s analysis,” but also creates “a **rebuttable presumption** that a high-level official’s deposition represents a significant burden.” *Id.* (emphasis added). And courts across the country are in agreement. *See, e.g., Harris v. Computer Assocs. Int’l, Inc.*, 204 F.R.D. 44, 46 (E.D.N.Y. 2001) (“When a vice president can contribute nothing more than a lower level employee, good cause is shown to not take the deposition.”); *Evans v. Allstate Ins. Co.*, 216 F.R.D. 515, 518–19 (N.D. Okla. 2003) (same); *Folwell v. Hernandez*, 210 F.R.D. 169, 173 (M.D.N.C. 2002)

(same); *Baine v. Gen. Motors Corp.*, 141 F.R.D. 332, 335 (M.D. Ala. 1991) (prohibiting apex deposition because “[i]t has also not been demonstrated that [the apex] has any superior or unique personal knowledge” of material issues of liability).

Plaintiffs seek to avoid this mountain of authority and instead rely on a non-binding decision from the Sixth Circuit, which has not been adopted or cited by courts in the Third Circuit. Plaintiffs’ reliance is misplaced for multiple reasons. First, Plaintiffs incorrectly state that it is “the only published federal appellate decision addressing the ‘apex doctrine,’” Opp. at 23-24. but, it is well understood that *Salter v. Upjohn Company*, 593 F.2d 649 (5th Cir. 1979) constitutes the original—and favored—application of the apex doctrine, even if it did not use the term “apex doctrine.” See *Roman*, 2007 WL 4893479, at *1 n.1 (referring to *Salter* as “the leading case on ‘apex depositions’”). More recently, in *Thomas v. Int’l Bus. Machines*, 48 F.3d 478 (10th Cir. 1995), the Tenth Circuit affirmed the grant of a protective order precluding the deposition of the defendant’s corporate chairman because “[n]othing in the record indicates that [defendant] did not make available for deposition” lower-level supervisors with knowledge of the matter. *Id.* at 483.

Second, notwithstanding Plaintiffs’ misstatement that *Serrano v. Cintas Corp.*, 699 F.3d 884 (6th Cir. 2012) is “the only published federal appellate decision addressing the ‘apex doctrine,’” *Serrano* does not help Plaintiffs. In *Serrano*, the Sixth Circuit provided two main reasons for overruling a protective order. First, “the

magistrate judge ... *failed to analyze* ... what harm [the CEO] would suffer by submitting to the deposition.” *Id.* at 902 (emphasis added). Second, the CEO’s testimony was found “likely to be highly probative” because the CEO’s statements “suggest[ed] high-level-corporate awareness of Cintas’s failure to hire females ... and this [went] to the heart of what the EEOC will seek to prove” under its Title VII discriminatory “pattern-or-practice” claim. *Id.*

This case is distinguishable from *Serrano* on both grounds. The ZHP Parties have argued that deposing lower level employees instead of Mr. Chen “would be less burdensome,” Open. Br. at 1, that Mr. Chen’s deposition would “impose a heavy burden” and “would unquestionably be duplicative and cumulative,” *id.* at 14, 19, and that “Mr. Chen ... **only** possess[es] duplicative, cumulative information about the highly technical subjects at issue,” *id.* at 28, **if any**. Thus, unlike in *Serrano*, this Court’s grant of a protective order would fall squarely within the parameters of Rule 26, and would not deprive Plaintiffs of testimony from a uniquely knowledgeable and “highly probative” witness because Mr. Chen’s deposition would be unduly burdensome, and at best would provide testimony that is cumulative, and duplicative of that of the employees with the most substantive knowledge (whose documents have been produced and whose depositions have already been taken).²

² This case is also distinguished from *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 2:13-MD-02436, 2014 WL 3035791 (E.D. Pa. July 1, 2014), because in that case the record showed that the defendant’s corporate

Plaintiffs also try to work around the apex doctrine by claiming that the Court already ordered Mr. Chen's deposition and decided this issue. Opp. at 1. But Plaintiffs misinterpret the plain meaning of Judge Schneider's words. Judge Schneider *acknowledged that Mr. Chen's deposition might be unnecessary* depending upon the deposition testimony of the other 17 ZHP Party witnesses. Hrg. Tr. 12-22-20 at 41:7-10 (THE COURT: "[I]f other depositions are taken, you might have a better record to show, in fact, that this testimony is, in fact, duplicative, cumulative, or nonmaterial," and "*after a sufficient deposition record is developed*, ZHP is granted leave to file a Motion for Protective Order to quash Mr. Chen's deposition.") (emphasis added). See Open. Br. at 13.

Plaintiffs' claim that the ZHP Parties should have submitted a declaration from Mr. Chen under Rule 26 is also misplaced. Opp. at 25. No declaration is required given the expansive record of testimony and documents provided by ZHP, its custodians and deponents that so clearly demonstrates that Mr. Chen has no material involvement in the facts at issue. See *Galmines*, 2015 WL 4973626, at *2 (prohibiting apex deposition without a declaration from the apex); *George v.*

president had "knowledge that is unique to him and which could not be obtained through the depositions of ... employees not quite at the 'apex.'" *Id.* at *3. Here, Plaintiffs' speculation that Mr. Chen has "unique" knowledge is belied by the record. Again, the standard is not whether Mr. Chen has any knowledge about any of the facts at issue. Plaintiffs must show Mr. Chen has knowledge so unique that it cannot be obtained from any source that would be less burdensome.

Pennsylvania Tpk. Comm'n, No. 1:18-CV-766, 2020 WL 2745724, at *3 (M.D. Pa. May 27, 2020) (same); *Pollock v. Energy Corp. of Am.*, No. CIV.A. 10-1553, 2015 WL 757458, at *8 (W.D. Pa. Feb. 23, 2015) (same).

In sum, this Court, consistent with courts within this Circuit, has applied the apex doctrine to bar an apex deposition in the exact circumstances presented in this case. Because the apex doctrine applies, Plaintiffs were required to rebut the presumption of undue burden by demonstrating that Mr. Chen has unique knowledge that could not have been obtained in a less burdensome manner. As discussed below, they have failed to do so.

II. PLAINTIFFS' OPPOSITION FAILS TO IDENTIFY EVIDENCE REBUTTING THE PRESUMPTION AGAINST MR. CHEN'S DEPOSITION UNDER THE APEX DOCTRINE

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Opp. at 22-23. Plaintiffs conclude their

factual section with the claim that:

Mr. Chen has to account for key matters he was at the heart of, and confirm what he knew and when, including but not limited to the inadequate risk assessments of the TEA and zinc chloride processes, the decision to develop the contaminating zinc chloride process, the decision to hide the contamination in order to maximize corporate profits, and the grudging disclosure only when Novartis forced ZHP to do so.

Opp. at 23.

Mr. Chen personally is not a defendant in this case, so Plaintiffs' claim that he must personally "account for" anything is mere rhetoric. The ZHP Parties—the actual defendants—are bound by the 30(b)(6) witnesses' testimony. Further, not only is the assertion that Mr. Chen was "at the heart of" the any issue material to this case bald speculation and fabrication, but Plaintiffs have already obtained, or had ample opportunity to obtain, extensive testimony about each and every "key matter" listed above:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

After all of this testimony, no matter how many times they repeat the same rhetoric, Plaintiffs have failed to uncover any evidence that Mr. Chen was "at the heart of" or had any unique knowledge of any of the matters they have highlighted. Nor have they rebutted clear and ample evidence that others in positions of responsibility beneath Mr. Chen, all of whom were deposed, who had direct control over and first-hand knowledge of these matters, testified and were fully available to respond to Plaintiffs' questions about each of these subjects. Mr. Chen's knowledge,

if any, would have been derivative of those beneath him in the organization, and not unique, and wholly duplicative of the evidence that has already been presented in this case's massive deposition, documentary and factual record.

Not surprisingly, the Opposition repeats the same contentions that Plaintiffs previously alleged, and the ZHP Parties rebutted, in their Opening Brief and Supplemental Brief:

- Relying on an organization chart, Plaintiffs summarily claim, without factual support or evidence, that Mr. Chen is the “linchpin” connecting the ZHP Parties and its U.S. affiliates. Opp. at 2. But the ZHP Party witnesses have already testified to the role of all of the entities within the ZHP organization. See Open. Br. at 17-19; Supp. Br. at 5-6.

 See Supp. Br. at 5-6.³

- Plaintiffs inappositely claim that Mr. Chen's resume and background as a chemical engineer proves that he “effectively leads all of ZHP's departments and is responsible for coordinating and synthesizing their disparate activities.” Opp. at 2-3. This claim completely misses the mark and does not in any way establish that Mr. Chen has unique knowledge that cannot and could not have been obtained from lower-level witnesses. Plaintiffs have already deposed seventeen ZHP Party witnesses, including nine department heads and lower-level employees at each ZHP Party entity related to the material issues in this case, about 59 different 30(b)(6) topics spanning all relevant departments across the ZHP Party entities. See Open. Br. at 2-4. Plaintiffs have also

³ If Plaintiffs' inclusion of photos of Mr. Chen that appear on the PrinJohnson Facebook page are meant to further their argument that Mr. Chen possesses unique knowledge about PrinJohnson's interaction with the other ZHP-related entities, this is refuted by the fact that Plaintiffs had the opportunity to, and did, depose numerous executives of PrinJohnson about this topic. See Open. Br. at 18-19.

deposed seven other ZHP Party witnesses from all key departments in their individual capacity, including Jun Du, *who repeatedly testified that the substantive decision-making in this case's key areas was made by the principals in the relevant departments, and not ZHP's board or General Manager, Mr. Chen.* See Supp. Br. at 3-4.

- Plaintiffs claim that Mr. Chen's occasional attendance at FDA plant inspections as the most senior executive at the company illustrates that he played a central role in these inspections, the ZHP Parties' interactions with the FDA or the company's responses to those inspections. Opp. at 3. Other than Mr. Chen's attendance at certain opening meetings and closing meetings, Plaintiffs have not produced evidence to support this speculative allegation, despite now having had the opportunity to depose no less than *eleven* ZHP Party witnesses on this topic. See Open. Br. at 20-23; Supp. Br. at 6-8.

[REDACTED]

- [REDACTED]. See Opp. at 3-4. Yet again, Plaintiffs have failed to present any evidence to support these unfounded claims despite having obtained testimony from *at least eight* ZHP Party witnesses regarding these topics. See Open. Br. at 23-25; Supp. Br. at 9-10. Plaintiffs also had the opportunity to depose Jie Wang, who was specifically designated to testify as ZHP's corporate representative on several 30(b)(6) topics relating to manufacturing costs. See Supp. Br. at 9-10.

•

[REDACTED]

•

[REDACTED]

⁴, three of whom were members of the so-called “Recall Group”⁵ that Plaintiffs have emphasized multiple times in their briefing requesting Mr. Chen’s deposition. *See* Opp. at 4-8; Open. Br. at 26-27; Supp. Br. at 10-11. [REDACTED]

[REDACTED]. Br. at 26-27. Plaintiffs had the opportunity to question ZHP Party 30(b)(6) and fact witnesses extensively about every aspect of the valsartan recall, including Mr. Chen’s role in interacting with regulatory authorities and communicating with customers, including Novartis and Teva about the recall, and they have failed to produce any testimony that Mr. Chen possesses unique information that would not be duplicative of the testimony already given.

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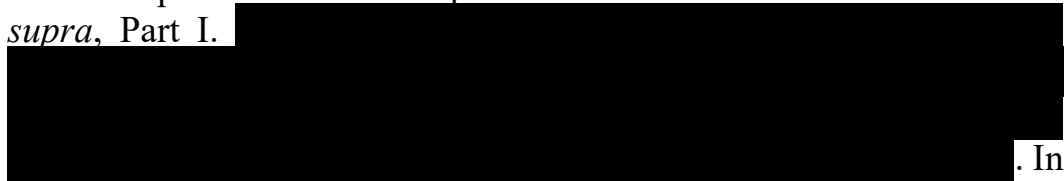
[REDACTED]

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- In attempting to shirk their burden under the apex doctrine, Plaintiffs claim several ZHP Party witnesses should have provided more testimony about Mr. Chen, *see* Opp. at 19-22, but as demonstrated above, Plaintiffs are required to rebut the presumption against Mr. Chen's deposition under the apex doctrine and have failed to do so. *See supra*, Part I.



. In the absence of specific evidence that Mr. Chen possesses first-hand or unique knowledge about any of the material issues in this case that could not have been derived by the deposition of others beneath him in the ZHP organization, Plaintiffs have not rebutted the presumption of the apex doctrine.

Finally, Plaintiffs have failed to provide any law or valid argument opposing the ZHP Parties' alternative request to hold the motion in abeyance until the additional discovery Plaintiffs have requested is completed.

CONCLUSION

WHEREFORE, for all of the foregoing reasons, and those in the Opening Brief and Supplemental Brief, incorporated by reference herein, the ZHP Parties request that the Court grant their motion for protective order or hold the motion in abeyance until the additional discovery Plaintiffs have requested is completed.

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Respectfully submitted,

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